EXHIBIT 29

L. Application to Medicare

Comment: One commenter specifically requested clarification that the alternative selected by the Department for the final rule would not apply to the Medicare program and that hospitals and hospital-based skilled nursing facilities would be exempt under Medicare.

Response: As we stated in the NPRM, we are deleting the references to the MAC program contained in the Medicare regulations concerning allowable costs for drugs. (In the NPRM, we noted that we would delete § 405.433. However, that regulation has since been redesignated and is now located at § 413.110. Thus, in this final rule, we are deleting § 413.110.) The upper limits for drugs contained in this final rule pertain only to the Medicaid program. They do not apply to hospitals and hospital-based skilled nursing facilities under Medicare.

IV. Provisions of the Final Regulations

In this final rule, we have attempted to: (1) Respond to the public comments on the NPRM; (2) provide maximum flexibility to the States in their administration of the Medicaid program; (3) provide responsible, but not burdensome Federal oversight of the Medicaid program; and, (4) take advantage of savings resulting from the availability of less costly, but safe and effective, generic drug substitutes.

To accomplish this, we are drawing from various aspects of the proposals. The Federal upper limit standard we are adopting for certain multiple source drugs is based on the application of a specific formula similar to that described in the NPRM. The upper limit for other drugs is similar to that in the NPRM in that it retains the EAC limits as the upper limit standard that State agencies must meet. However, this standard is applied on an aggregate rather than on a prescription specific basis.

We want to emphasize that as a result of our adopting aggregate limits as the upper limit standards, State agencies are encouraged to exercise maximum State flexibility in establishing their own payment methodologies. We do not intend that our adoption of the formula approach to set limits for multiple source drugs be construed as an indicator of the Federally preferred payment system. The use of the formula approach is primarily due to the straight-forward application and administrative ease in setting upper limits. We encourage State agencies to establish any program that will substitute lower-priced alternatives for drugs. We hope that the State agencies will be innovative in these programs and find ways to assure the availability at reasonable prices of multiple-source drugs. One way they could do this would be to encourage retail pharmacy participation in the Medicaid program by permitting them to retain profits from the sale of listed drugs to Medicaid recipients. Other alternative payment systems could include, for example, contracting on a competitive basis for pharmaceutical services with selected pharmacies to which recipients may go for drugs without incurring a copayment or a system which entails charge screens and/or mandatory discounts. Additionally, State agencies may initiate or retain already existing so-called "mini-MAC" programs, which they have established on specific drugs either at levels lower than those established under the current Federal MAC limits or on drugs not now covered by MAC limits. This system of aggregate upper limits will allow State agencies to alter payment rates for specific listed drugs without first having to obtain permission from HCFA. The agencies then will be able to respond rapidly to sudden price fluctuations, which may threaten the supply of specific drugs on the HCFA list, without having to pursue a cumbersome approval process. A final advantage of the aggregate limit methodology is the ease of administration at the Federal level and the lack of administrative burden on State programs.

A. Multiple Source Drugs

The Federal upper limit standard that we have adopted for certain multiple source drugs is based on an aggregate payment amount equal to an amount that includes the ingredient cost of the drug calculated according to the formula described below and a reasonable dispensing fee. HCFA will determine to which drugs the formula will be applied. The listing of these drugs and any revisions to the list will be provided to State agencies through Medicaid program issuances on a timely, periodic basis (possibly semi-annually). The effective date of the new prices will be subsequent to the issuance of the listing. As did the NPRM, the final rule will specify that the drugs to which this formula will be applied must have been evaluated as therapeutically equivalent by the FDA. Similar to the NPRM, the final rule will specify that at least three suppliers list the drug in a national compendium. The NPRM stated that three suppliers would advertise the drug in the *Red Book* or *Blue Book*.

The formula to be used in calculating the upper limit of payment for certain multiple source drugs will be 150 percent of the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules (or if the drug is not commonly available in quantities of 100, the package size commonly listed), or in the case of liquids, the commonly listed size. As we stated in the NPRM, we chose the markup of 150 percent in order to meet the following two objectives: (1) That the markup be high enough to assure that pharmacists can normally obtain and stock an equivalent product without losing money on acquisition costs of incurring the expense of departure from normal purchasing channels, and (2) that the markup not be so high as to cost the Medicaid program unnecessary money. In other words, the 150 percent is intended to balance the interests of both pharmacists and the government in achieving efficiency, economy and quality of care as specified in section 1902(a)(30) of the Act.

In the NPRM, we stated that we would use the *Red Book* or *Blue Book* to determine the least costly therapeutic equivalent that can be purchased by pharmacists. In this final rule, however, we are deleting the reference to these specific sources and are specifying that we will publish and use the list of all current editions (or updates) of acceptable published drug compendia available for sale nationally. Although State agencies will need to calculate or impute a dispensing fee (if they do not pay for the dispensing fee separately) in order to determine if they meet the upper limit standard for certain multiple source drugs, we are deleting the current § 447.333 that recommends how agencies are to establish the dispensing fee.

As originally proposed under all options, this final rule will provide that if a physician certifies that a brand name drug is medically necessary, the upper limit for payment based on the formula will not apply. The upper limit for payment of "other drugs" (discussed in section IV.B) will apply.

In the future, the formula approach to setting an upper limit will be evaluated. We are aware of several State agencies now in the process of negotiating competitive bids for discounts or rebates from drug manufacturers and suppliers. Other agencies are considering selective contracting with providers or pharmacies (preferred provider organizations). Additionally, the interaction of competitive pricing and creative marketing may cause dynamics in the market that would necessitate a revision of our policy. Thus, we will monitor the implementation of this